

### REMARKS

Applicants thank the Examiner for the careful consideration given to this application. Reconsideration is now respectfully requested in view of the amendment above and the following remarks.

Claims 1-26 and 28-36 are pending in this application. Claims 1 and 25 are independent claims. Claims 1, 4-6, 8-12, 14, 16, 18-20, 22, 25, 28-31, and 33-35 are amended. Claim 27 is cancelled without prejudice or disclaimer. New Claim 36 is added. Reconsideration and allowance of the present application are respectfully requested.

### Specification

The abstract is objected to because of informalities. Applicants have now canceled the original abstract and have provided a new abstract that addresses the informalities. Therefore, Applicants respectfully request that the Examiner withdraw the objection.

### Priority

At page 2, the Office Action acknowledges Applicants' claim for foreign priority. Applicants are in the process of obtaining the necessary certified copies of the priority applications. In the meantime, informal copies of these applications are being provided.

### Drawings

At pages 2-3, the Office Action objects to the drawings based on an alleged lack of showing of a claimed feature. Applicants respectfully traverse this objection. The Office Action alleges that the "control means" is not shown in the drawings. However, Applicants respectfully submit that the specification, e.g., beginning at the bottom of page 16 (i.e., in the section entitled, "Manipulation of the aerosol"), describes how characteristics of the aerosol, such as uniformity and/or mean particle size, may be manipulated. Within this section of the application, it is described how control of such characteristics may be accomplished, according to embodiments of the invention. For example, at pages 17-18, it is described how such control/manipulation of aerosol characteristics may be performed by adding or removing energy, e.g., by a condensation process or by an evaporation process. This is further discussed, e.g., at page 39, where Figures 4

and 5 are discussed, and where it is discussed how such control processes may be accomplished using condenser 19 and/or dilution chamber 20. Therefore, Applicants respectfully submit that they have adequately shown “control means” in the drawings and that no amendments to the drawings or claims are necessary. Applicants respectfully request that the Examiner withdraw the objection.

#### **Claim Objections**

Claims 5-24 and 28-35 are objected to because of informalities based on improper multiple-dependent claims. Applicants have amended the claims to address such issues. Therefore, Applicants respectfully request that the objections to Claims 5-24 and 28-35 be withdrawn.

#### **Claim Rejections under 35 U.S.C. § 112**

Claims 1-4 and 25-27 stand rejected under 35 USC § 112, second paragraph, as being indefinite. This rejection is respectfully traversed for at least the following reasons.

Applicants initially note that Claim 3 has been amended to address the issue raised by the Office Action.

Regarding Claim 1, as discussed above, Applicants respectfully submit that sufficient description has been provided for the claimed “control means.” Regarding “supply means,” Applicants respectfully submit that this is described, e.g., at pages 27 ff., beginning at the last line of page 27 (“Adding a substance to the aerosol”), and this is also shown schematically at least in Figure 6; see, also, page 39, line 26 to page 40, line 3.

Regarding Claims 25 and 26, the Office Action states, “the claimed method steps are unclear as there is not any structure recited which is used for performing the claimed method steps which are therefore unclear.” Office Action at 4. Applicants note, first, that the steps of the method are presented beginning at page 13 of the specification, and exemplary structures that may be used to perform the method are demonstrated in the drawings, which are described, e.g., beginning at page 37 of the specification. Additionally, it is noted that it is not necessary to disclose a structure to support method claims.

Claims 2, 4, and 27 were rejected based on the rejections of one or more of the claims discussed above, and therefore, these rejections have also been addressed.

Therefore, Applicants respectfully request that the rejections of Claims 1-4 and 25-27 under 35 U.S.C. § 112 be withdrawn.

**Claim Rejections under 35 U.S.C. § 102**

Claims 1-4, 25 and 27 stand rejected under 35 U.S.C. § 102(a) as being anticipated by International Publication No. WO 03/094640 to Esser (hereinafter "Esser"). This rejection is moot with respect to Claim 27, given the cancellation of Claim 27. This rejection is respectfully traversed with respect to the remaining claims, for at least the following reasons.

Independent Claim 1, as amended, recites:

1. Inhalation device for creating an aerosol, comprising:
- aerosol means, for creating an aerosol in the device,
  - control means, for adjusting the state and condition of the aerosol in order to manipulate the characteristics of the aerosol, including its uniformity and/or its mean particle size,
  - an opening, for releasing the aerosol from the device, and
  - supply means, for adding a substance to the aerosol, prior to or upon release of the aerosol from the opening and after an adjustment of the state and condition of the aerosol by the control means, in order to release the substance from the opening using the aerosol as a carrier.

Independent Claim 25, as amended, recites:

25. Method for creating an aerosol in an inhalation device, comprising the steps of:
- a) creating an aerosol by means of aerosol means in the inhalation device,
  - b) adjusting the state and condition of the aerosol, in order to manipulate the characteristics of the aerosol, including at least its uniformity and/or its mean particle size,
  - c) releasing the aerosol from an opening of the device, and
  - d) adding a substance to the aerosol, prior to or upon release of the aerosol from the device in order to release the substance from the opening using the aerosol as a carrier, wherein step d) is executed after execution of step b).

Applicants respectfully submit that Esser fails to disclose at least “supply means, for adding a substance to the aerosol, prior to or upon release of the aerosol from the opening and after an adjustment of the state and condition of the aerosol by the control means,” as recited in independent Claim 1, or “adding a substance to the aerosol, prior to or upon release of the aerosol from the device in order to release the substance from the opening using the aerosol as a carrier, wherein step d) is executed after execution of step b),” as recited in independent Claim 25 (i.e., the recitation of canceled Claim 27 has been incorporated into independent Claim 25).

The Office Action, noting page 5, alleges that the claimed supply means corresponds to element 15 of Esser. Office Action at 5. In paragraph 28 of Esser (references are to U.S. Patent Application Publication No. 2005/0211243, similar to in the Office Action), element 15 is described as a “active ingredient container,” and it is described as being connected to a mixing chamber 11 via a hollow needle 16. Esser at paragraph 28. Applicants note that the Office Action addresses the order of steps only with respect to (canceled) Claim 27, not with respect to Claim 1, and the Office Action refers to paragraphs 31 and 34 of Esser. Office Action at 6. Therefore, this discussion will tie together these various aspects of the Office Action.

Paragraph 31 of Esser recites the following:

In order to inhale, the inhaler's mouth piece 4 is placed to the mouth and air is sucked into the inhaler via the inlet 2. In the process, the sucked-in air flows past the membranes 7, 8 and reacts on the membranes 7, 8 with the hydrogen, so that water vapor is generated and an air/water vapor mix results. At the same time, the current produced by the fuel cell in that reaction is conducted to the spiral-wound filament, so that the fluid located in the hollow needle and containing the inhalation additives is evaporated. Due to the excess pressure thus created, the pressure relief valve 16 opens so that vapor containing inhalation additives can escape. This vapor is admixed to the air/water vapor mixture in the mixing chamber 11, so that a mixture of air, water vapor and inhalation additives can be breathed in through the mouth piece.

Esser at paragraph 31. Paragraph 34 recites:

Likewise, additional adjustment and control mechanisms can be provided. While the fuel cells available today are generally self-regulating subject to the supplied

air flow, there might be a need to control the hydrogen supply, depending on the area of application. It is also possible, for example depending on the temperature and/or the relative humidity of the air/water vapor/inhalation mixture, to provide an adjustable fresh air supply in the mixing chamber, with which the mixture in the mixing chamber can be cooled. Of course any necessary cooling can also be achieved through a heat exchanger.

Esser at paragraph 34. Noting these paragraphs, and particularly, paragraph 34, it becomes clear that, in Esser, the alleged “manipulating the aerosol” in Esser is performed *after*, not prior to, the addition of the inhalation mixture. This is particularly evident in view of the following portion of paragraph 34 of Esser: “It is also possible, for example depending on the temperature and/or the relative humidity *of the air/water vapor/inhalation mixture*, to provide an adjustable fresh air supply *in the mixing chamber*, with which the mixture in the mixing chamber can be cooled.” Esser at paragraph 34 (emphasis added); see, also, the latter portion of paragraph 31 (“This vapor is admixed to the air/water vapor mixture in the mixing chamber 11”). Hence, Esser does not disclose, or even suggest, “adding a substance to the aerosol... after an adjustment of the state and condition of the aerosol by the control means,” as recited in independent Claim 1 (and similarly in independent Claim 25); rather, Esser teaches that the “air/water vapor/inhalation mixture” is manipulated, after addition of the substance (i.e., the “inhalation” portion of this mixture).

Consequently, the Office Action fails to support a *prima facie* case that independent Claims 1 and 25 are anticipated by Esser, and similarly, for at least the same reasons, that dependent Claims 2-4 are anticipated by Esser (noting that Claim 27 has been canceled and incorporated into Claim 25). Therefore, Applicants respectfully request that this rejection of Claims 1-4, 25 and 27 under 35 U.S.C. § 102 be withdrawn.

#### **Claim Rejections Under 35 U.S.C. §103**

Claim 26 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over International Publication No. WO 03/094640 to Esser (hereinafter “Esser”). This rejection is respectfully traversed for at least the following reasons.

Claim 26 depends from independent Claim 25, which has been discussed above. Furthermore, the Office Action relies on the application of Esser in the rejection of Claim 25 under 35 U.S.C. § 102 as teaching the corresponding elements of Claim 26. No further reference is cited here. Hence, the above discussion applies here, as well, and the Office Action fails to support a *prima facie* case of the obviousness of Claim 26 based on Esser.

Therefore, Applicants respectfully request that this rejection of Claim 26 under 35 U.S.C. § 103 be withdrawn.

#### **Disclaimer**

Applicants may not have presented all possible arguments or have refuted the characterizations of either the claims or the prior art as found in the Office Action. However, the lack of such arguments or refutations is not intended to act as a waiver of such arguments or as concurrence with such characterizations.

**CONCLUSION**

In view of the above, consideration and allowance are respectfully solicited.

In the event the Examiner believes an interview might serve in any way to advance the prosecution of this application, the undersigned is available at the telephone number noted below.

The Office is authorized to charge any necessary fees to Deposit Account No. 22-0185.

Applicant believes no fee is due with this response other than such fees as may be indicated in an accompanying paper. However, if any further fee is due (including if such paper is inadvertently omitted), please charge our Deposit Account No. 22-0185, under Order No. 22407-00041-US, from which the undersigned is authorized to draw.

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Respectfully submitted,

Electronic signature: /Jeffrey W. Gluck/  
Jeffrey W. Gluck  
Registration No.: 44,457  
CONNOLLY BOVE LODGE & HUTZ LLP  
1875 Eye Street, NW  
Suite 1100  
Washington, DC 20006  
(202) 331-7111  
(202) 572-0322 (Direct Dial)  
(202) 293-6229 (Fax)  
Attorney for Applicant